Todd Pickles (SBN CA 215629)
GREENBERG TRAURIG, LLP
1201 K Street, Suite 1100
Sacramento, California 95814
Telephone: 916.442.1111
Facsimile: 916.448.1709
picklest@gtlaw.com

Defendant Mark Schena

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UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA

United States of America, CASE NO. 5:20-mj-70721-MAG Defendant's Brief Regarding Bond and Plaintiff. Conditions of Release v. Mark Schena, DATE: June 17, 2020 10:30 a.m. TIME: Courtroom B. 15th Floor Defendant. CTRM: Honorable Laurel Beeler JUDGE:

Defendant Mark Schena hereby submits this brief regarding the conditions of release. Specifically, Dr. Schena requests that the Court modify the special conditions of release, which presently contain vague or ambiguous language, to permit him to perform technical work and engage in clinical operations in the laboratory at Arrayit Corp. or, in the alternative, find that Dr. Schena's work in the laboratory is not prohibited by the special conditions of release. Dr. Schena also opposes any efforts to increase the bond amount, including requiring security, or to impose additional conditions of release.

A. This is the First Time the Bond or Conditions of Release Have Been Reviewed by the Court With Benefit of Defense Counsel

Dr. Schena was arrested on June 9, 2020 on a criminal complaint. Apparently due to the time it took to transport and process him into federal custody, Dr. Schena was not placed onto the Court's calendar for an initial appearance and arraignment until June 10, 2020. Even then, there was apparently an error at

Santa Rita such that Dr. Schena was not present for the court proceedings on June 10, 2020. Fortunately,

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the Court ordered Dr. Schena released, imposing the conditions requested by the government, including a bond in the amount of \$2,000,000, and with the standard and special conditions of release. See ECF No. 7. At the time those conditions were imposed on June 10, 2020, Dr. Schena had not had the opportunity to even meet with his Court-appointed counsel. Dr. Schena retained his current counsel at Greenberg Traurig the following day June 11, 2020. When Dr. Schena had his arraignment and initial appearance later on June 11, 2020, counsel advised the Court that he had only recently been retained and had not yet had the chance to sufficiently consult with Dr. Schena or even review with him the terms already imposed. The Court indicated that the bond amount, as well as the special conditions and terms of release, would be reviewed in a further hearing before this Court. Dr. Schena has complied with those terms since imposed. However, a review of Dr. Schena's history and characteristics and the allegations in the affidavit filed in this matter demonstrates that the conditions and terms imposed are not the "least restrictive further conditions, or combination of conditions" to assure Dr. Schena's attendance at all proceedings or to protect the public.

B. There is No Danger of Flight or Non-Appearance

There is no colorable argument that Dr. Schena poses a risk of flight. He has resided in California continuously since 1980 when he arrived for college at University of California, where he obtained his bachelor of sciences degree. Dr. Schena has owned the same home here for twenty years with his wife Rene, also a California resident. His family is located either in California or in Upstate New York. Dr. Schena has not traveled abroad in almost three years, does not have any substantial overseas ties, and has surrendered his passport to Pretrial Services as ordered by the Court. He has no criminal history at all.

Dr. Schena has a Ph.D. in Biochemistry from the University of California, San Francisco. Dr. Schena has worked at Arrayit since approximately 1999. Arrayit is a commercial laboratory located in Sunnyvale, California. Arrayit is certified by the California Department of Public Health and the Center for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments (CLIA) of 1988. Dr. Schena is an officer of the company and also the Laboratory Manager. Other than the fact that the allegations mention COVID-19, the defense suspects that Dr. Schena would have been released on his personal recognizance or otherwise under 18 U.S.C. § 3142(b). Certainly a \$2 million bond dollar appears 1

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extreme given the history and characteristics of Dr. Schena and the absence of any risk of flight. Increasing this amount, or imposing a requirement of security, would further be unreasonable. If anything, the Court should reduce the amount of the bond. Nonetheless, the current bond amount, with Rene Schena as cosigner if that is determined necessary by the Court, are more than sufficient to ensure Dr. Schena's appearance at all court proceedings and compliance with the other terms of release.

C. Special Conditions Potentially Prohibiting Dr. Schena From Working Are Unsupported

Two of the four special conditions of release are vaguely worded and potentially would prohibit Dr. Schena from effectively working at Arrayit at all. To the extent this is how the government interprets them, the conditions are not the "least restrictive," particularly when considering the untested allegations in the complaint.

Specifically, the conditions of release impose the following special conditions:

Defendant shall not engage, directly or indirectly, in any COVID-19 testing that is not FDA approved or emergency use authorized. Defendant shall not bill or cause to be billed any health care insurance plan, other than for his own medical care. Defendant shall not liquidate, sell, trade, or otherwise transfer shares or securities in Arrayit. Defendant shall not have contact with any victim or witness in the case.

Dr. Schena does not object to the latter two conditions, with the request that the government provide to him a list of those it considers to be a "victim or witness in the case." With the first two conditions, these could be construed to mean that Dr. Schena cannot work within the laboratory at Arrayit in connection with performing the numerous other tests that are ordered by physicians in the community.

As noted above, Dr. Schena is, among other things, the Laboratory Manager at Arrayit. In that role, Dr. Schena is involved in the technical and clinical operation of processing specimens. A third party is responsible for making the test result available to physicians who have prescribed testing for their patients for diagnostic and treatment purposes. A different third party vendor submits all claims on behalf of Arrayit to the applicable third-party payor (i.e., group health plan, HMO, etc.) in connection with the tests performed by Arrayit. Dr. Schena himself is not involved in payor negotiations or any billing aspect. Rather, his work is in the laboratory facility as a scientist, where he is responsible for technical work and management of the clinical operations. He is also responsible for quality control and compliance with federal and state regulatory standards. Nonetheless, because the conditions refer to Dr. Schena engaging

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in conduct that may "caused to be billed," there is uncertainty as to whether it applies to his any or all of technical work. Dr. Schena should be permitted to continue his technical work, and nothing in the complaint supports prohibiting such conduct.

The gravamen of the unexamined allegations in the complaint regarding testing and billing is that Dr. Schena allegedly conspired with a particular physician for that physician to submit tests to Arrayit even though the tests were unnecessary, and that the physician gave Dr. Schena his/her identification number and that test were submitted without the physician's knowledge. Putting aside the fact that (a) all that is known about the physician is that he/she is cooperating with the government to obtain a reduced sentence; (b) there is no discussion at all as to the source of the physician's knowledge; and (c) much of the allegations refer generally to "Arrayit" or "others" or an "executive" at Arrayit, even if these were true they would not support prohibiting Dr. Schena from working in the laboratory. Presumably no tests have been submitted by this physician since he began working with the government, and any alleged tests under the physician's name can be removed from the queue if they ever were there. Prohibiting Dr. Schena from working in the laboratory to perform any testing is thus not the "least restrictive" condition given the limited historical allegation of processing unnecessary tests submitted by a particular physician.

The other theory of criminal liability in the complaint is that Dr. Schena allegedly made various statements to the public and others about COVID-19 testing or other aspects of Arrayit that were allegedly inaccurate. Again, putting aside the fact that much of this appears to have been drawn from unattributed posts on a public investor message board, or parsing particular tweets that are attributed by the government to Dr. Schena, much of this conduct is from 2019 or before and, equally saliently, this does not relate to Dr. Schena's work in the laboratory. Notwithstanding the above, as noted, Dr. Schena does not object to a prohibition on communications, including tweets or on other venues. Thus, the government's concern about misinformation is already adequately addressed by a different condition of release. On the other hand, barring Dr. Schena from the laboratory has no connection with the allegations of inaccurate statements.

Finally, the complaint includes allegations about the COVID-19 testing performed by Arrayit and that it is somehow not in accordance with the standards by the Federal Food and Drug Administration (FDA) or results in false positives. To be clear, FDA has not "approved" any COVID-19 test in the United

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States, but rather there is only FDA "authorized" COVID-19 tests under emergency use authorization (EUA) which authorization is not required under FDA policy for tests developed and used in a CLIA-certified high-complexity laboratory such as Arrayit. Nonetheless, Arrayit has voluntarily submitted a pending EUA application with FDA that for its COVID-19 serology test because it has validated an antibodies test with nearly one hundred percent specificity and sensitivity (the allegations about the specificity and sensitivity of Arrayit's test for COVID-19 in the criminal complaint is inaccurate and out of date). The FDA and California regulatory bodies are the appropriate agencies to determine the efficacy of the serology testing by Arrayit; especially during the current shortage of clinical laboratories able to perform such testing across the country. Regardless, the present complaint and conditions of releases involve only Dr. Schena. Dr. Schena should be permitted to perform the work of a Laboratory Manager at Arrayit.

D. Conclusion

DATED: June 16, 2020

The Court should find that Dr. Schena's work in the laboratory as the Laboratory Manager at Arrayit is permitted under any terms and conditions of release. No further conditions should be imposed, including requiring security for the bond.

Respectfully,

GREENBERG TRAURIG, LLP

Ву

Todd Pickles

Defendant Mark Schena